



U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE  
STATEMENT**

Docket Number:  
1662/611051

Application Number  
10/622,905

Filing Date  
July 18, 2003

Examiner  
To Be Assigned

Art Unit  
To Be Assigned

Invention Title  
POLYMORPHIC FORMS OF NATEGLINIDE

Inventor(s)  
Ronit YAHALOMI et al.

Address to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on:

Date: 3-2-04

Signature: Bernadette DiGama

Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of U.S. patents and U.S. patent application publications listed on the modified PTO Form 1449 are not enclosed since the present application was filed after June 30, 2003. Copies of all foreign patent documents and non-patent literature listed on the modified PTO Form 1449 are enclosed. Please note disclosure of a purchase cited under "other documents."
3. Please note that reaction schemes of some of the foreign language art cited herein is provided in the background section of the invention.

4. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due the Commissioner is authorized to charge deposit account number 11-0600 for such fees. A copy of this communication is enclosed for charging purposes.

Dated: May 02, 04

By: Payam Moradian  
Payam Moradian (Reg. No. 52,048)

KENYON & KENYON  
One Broadway  
New York, New York 10004  
(212) 425-7200 (telephone)  
(212) 425-5288 (facsimile)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <b>PTO-1449</b>	ATTY. DOCKET NO. 1662/611051	SERIAL NO. 10/622,905
	APPLICANT Ronit YAHALOMI et al.	
	FILING DATE July 18, 2003	GROUP To Be Assigned



#### U. S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE*
	4,816,484	March 28, 1989	Toyoshima et al.			
	Re 34878	March 14, 1995	Toyoshima et al.			
	5,463,116	October 31, 1995	Sumikawa et al.			
	5,488,150	January 30, 1996	Sumikawa et al.			
	6,548,529	April 15, 2003	Robl et al.			
	6,555,519	April 29, 2003	Washburn			
	2001/0044584	November 22, 2001	Kensey			
	2002/0032149	March 14, 2002	Kensey			
	2002/0061835	May 23, 2002	Kensey			
	2003/0069221	April 10, 2003	Kosoglou et al.			
	2003/0078517	April 24, 2003	Kensey			
	10/614,266		Yahalomi et al.			7/3/03

#### FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 01/21159	March 29, 2001	PCT			N/A	
	WO 02/32854	April 25, 2002	PCT			Abs.	
	WO 02/34254	May 2, 2002	PCT			Abs.	
	WO 02/34285	May 2, 2002	PCT			N/A	
	WO 02/34713	May 2, 2002	PCT			Abs.	
	WO 02/40010	May 23, 2002	PCT			Abs.	
	WO 03/022251	March 20, 2003	PCT			N/A	
	WO 03/076393	September 18, 2003	PCT			N/A	
	WO 03/087038	October 23, 2003	PCT			N/A	
	WO 03/087039	October 23, 2003	PCT			Abs.	
	WO 03/093222	November 13, 2003	PCT			N/A	
	200200360	July 2, 2002	SK			Abs.*	

\* Application has not yet published; however, corresponding PCT application No. WO 01/21159 is enclosed.



## OTHER DOCUMENTS

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Hiroko Takesada et al., "Structure Determination of Metabolites Isolated from Urine and Bile after Administration of AY4166, a Novel D-Phenylalanine-Derivative Hypoglycemic Agent," Bioorganic & Medicinal Chemistry, Vol. 4, No. 10, 1996, pp. 1771-1781
	Hisashi Shinkai et al., "N-(Cyclohexylcartonyl)-D-phenylalanines and Related Compounds. A New Class of Oral Hypoglycemic Agents. 2," J. Med. Chem., Vol 32, 1989, pp. 1436-1441
	Xue-yan Zhu et al., "Study on Synthesis of Nateglinide," Hecheng Huaxue, Vol. 9, No. 6, 2001, pp. 537-540
	LI Gang et al., "A New Crystal Form of Nateglinide," Acta Pharmaceutica Sinica, Vol. 36, No. 7, 2001, pp. 532-534
	LI Gang et al., "Found a New Crystal Structure in Nateglinide by X-ray Powder Diffraction," Chinese Journal of Pharmaceutical Analysis, Vol. 21, No. 5, 2001, pp. 342-344
	A nateglinide having the enclosed XRD (see fig. 17) was purchased before July 3, 2002 in a foreign country from a supplier in another foreign country.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	